UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NORTH CAROLINA

PHILLIP J. SINGER, Individually and on Behalf of All Other Persons Similarly Situated, Plaintiff, v. TRANS1 INC., KENNETH REALI, JOSEPH P. SLATTERY, RICHARD RANDALL, and MICHAEL LUETKEMEYER, Defendants.	**Civil Action No.: 7:12-cv-00023-F** **JURY TRIAL DEMANDED**

[PROPOSED] SECOND AMENDED CLASS ACTION COMPLAINT

Lead Plaintiff Phillip J. Singer ("Plaintiff"), individually and on behalf of all other persons similarly situated, by his undersigned attorneys, for his complaint against defendants, alleges the following based upon personal knowledge as to himself and his own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through his attorneys, which included, among other things, a review of the defendants' public documents, conference calls and announcements made by defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Trans1 Inc.[1] ("Trans1" or the "Company"), analysts' reports and advisories about the Company, interviews with confidential informants, and information readily obtainable on the Internet. Plaintiff believes

[1] The company changed its name to Baxano Surgical from TranS1 Inc. on May 31 after it acquired Baxano Inc. On June 19, 2013, Defendants filed a Motion to Modify Case Caption to reflect the Company's corporate name change [Dkt. #45]. Plaintiff does not oppose the motion. For purposes of consistency, the complaint will continue to refer to the Company as "Trans1".

that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons other than defendants who purchased Trans1 securities between February 23, 2009 and October 17, 2011, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under the Securities Exchange Act of 1934 (the "Exchange Act") against the Company and certain of its top officials.

2. Trans1 designs, develops, and markets medical devices to treat degenerative disc disease affecting the lower lumbar region of the spine. Trans1 received its first 510(k) clearance from the Food and Drug Administration ("FDA") to manufacture, market, and sell its AxiaLIF line of products (collectively "AxiaLIF") in the fourth quarter of 2004, a clearance process that is less costly and requires less supportive clinical data than the FDA's Pre-Market Approval ("PMA") application process. AxiaLIF, which utilizes a "pre-sacral approach," is designed to provide the least invasive approach for surgeons to perform fusion and motion preserving surgeries in the L4/L5/S1 region of the spine. One of the unique characteristics of the AxiaLIF procedure is that it is performed straight up the tailbone, rather than through the anterior (front) portion of the spine. The patient is on his/her stomach throughout the entire procedure.

3. Trans1 derives its revenue almost ***entirely*** from sales of its AxiaLIF products and related surgical instruments. Moreover, Trans1 derives revenues through sharing in a portion of the insurance reimbursement (whether via federally funded Medicaid/Medicare or private insurance) received by surgeons for use of the AxiaLIF product. In other words, Trans1's financial viability rests on the successful sale of AxiaLIF to surgeons.

4. Trans1, like all medical device companies, primarily derives its revenues from surgeons who utilize the device in surgeries and are thereafter reimbursed for the procedure from private or federally funded insurance companies. Trans1's financial viability is directly linked to a surgeon's ability to get reimbursed for AxiaLIF. If insurance companies refused to reimburse surgeons for an AxiaLIF procedure, they would simply stop utilizing the device. In order to submit a procedure for reimbursement to an insurance company, providers must enter a code, known as a Current Procedural Terminology ("CPT")[2] code, which classifies the procedure and helps the insurance company determine whether it qualifies for reimbursement. Such codes are issued by the American Medical Association ("AMA"). Where applicable, the AMA often adopts the classification recommendation of the National Association of Spine Surgeons ("NAS").

5. Prior to 2009, surgeons using AxiaLIF obtained reimbursement from insurance companies using CPT codes reserved for spinal procedures that approach the anterior portion of the spine. This allowed surgeons to procure reimbursement for AxiaLIF unperturbed, securing a viable revenue stream for the Company. In 2008, however, a seismic shift occurred in AMA's coding for AxiaLIF which threatened the future viability of the Company. Specifically, the NAS concluded that AxiaLIF was not in fact a traditional anterior procedure, because it was performed straight up the tailbone, and not through the anterior portion of the spine. In other words, the AxiaLIF approach did not compare sufficiently to the traditional anterior approach used in other widely tested fusion surgeries. As a result of the NAS's conclusion, the AMA assigned a Category III (also known as an "experimental" or "T-Code") CPT code to AxiaLIF effective January 2009.

6. The new experimental designation by the AMA presented a serious threat to the Company's future revenue stream. Insurance companies generally do not grant reimbursement to

[2] CPT® is a registered trademark of the American Medical Association ("AMA").

surgeons for performing experimental procedures, opting to reimburse only those procedures identified as traditional ("Category I") by the AMA. Facing the risk of not getting paid for their work and not receiving reimbursement for procedures done with a costly device, surgeons shied away from using AxiaLIF, turning instead to other fusion surgeries where reimbursement was assured.

7. Desperate to maintain the Company's sole source of revenue, Defendants embarked on a campaign to encourage surgeons to disregard the Category III code and employ alternate, wholly inapplicable, CPT codes to receive reimbursement. Examples of this illicit campaign include Defendants: (1) forming a reimbursement committee to "coach" surgeons on how to avoid using the assigned Category III CPT code and utilize an inapplicable CPT code meant for anterior procedures; (2) holding conference calls with distributors during which they were trained on how to convince surgeons to use the CPT code for anterior procedures rather than the mandatory Category III code; (3) creating a template setting forth specific steps surgeons should take to avoid using the assigned Category III coding and fraudulently obtain reimbursement; (4) drafting and dispersing a Reimbursement Guide setting forth alternate codes to use in place of the mandatory Category III code; (5) promoting the use of the anterior CPT code rather than the assigned Category III code at the Company's National Meeting held in January 2009, attended by Defendant Randall; and (6) knowingly misrepresenting AxiaLIF as having been "approved for marketing" by the FDA for non-adjunct to fusion use in spinal fusion surgeries. Such blatant machinations directly violated the Federal False Claims Act, North Carolina False Claims Act, and other federal fraud and healthcare statutes, and were hidden from investors.

8. Defendants' deceptive tactics led to the filing of an action in the District of Maryland on April 21, 2011, by plaintiff and qui tam Relator Kevin J. Ryan, who was employed

by Trans1 Inc. from approximately July 1, 2008 to January 18, 2010 as a Clinical Sales Manager ("qui tam Complaint"). The allegations in that Complaint, which remained under seal until July 1, 2013, further corroborate the allegations contained herein. Specifically, the qui tam Complaint alleges that Trans1 "submitted and facilitated the submission of false and fraudulent claims, statements and/or documents to federal agencies by causing physicians and hospitals to submit improper claims for payment to Medicare and state health insurance programs and insurers." The Complaint claims that "the Federal Treasury and the State of North Carolina have been damaged in a substantial amount that is yet to be determined, currently estimated at approximately $20,000,000.00."

9. The qui tam action also caught the notice of regulators. On October 18, 2011, after the market closed, the Company revealed that it had received a subpoena from the Department of Health and Human Services ("DHHS"), Office of Inspector General. The subpoena, issued under the authority of the federal healthcare fraud and false claims statutes, requested documents for the period January 1, 2008 through October 6, 2011. The market had no question that the focus of the subpoena related to the companies reimbursement practices, given that insurance company reimbursement for AxiaLIF, Trans1's flagship product, accounted for a majority of its revenue. Indeed, an analyst report published one day after the announcement surmised with radar precision that the subpoena was triggered by "allegations by a disgruntled former employee" relating to the Company's illicit "reimbursement communications."

10. As a result of this disclosure, investors engaged in a massive selloff of Trans1 shares the following day, causing its share price to plummet $1.27 or more than 40%, on unusually heavy trading volume of 2.1 million shares.

11. Effective June 28, 2013, the Company entered into an agreement for $6 million to settle the government's claims ("Settlement"), which are virtually identical to those set forth herein, as well as the claims set forth against Trans1 in the qui tam Complaint. Specifically, the agreement settles claims that:

> (1) TranS1 knowingly caused providers to submit claims for minimally invasive AxiaLIF procedures using incorrect diagnosis or procedure codes, including codes intended for invasive ALIF procedures, such as 22558, or for unlisted spine procedures, 22899, which in some cases resulted in providers receiving greater reimbursement than that to which they were entitled; (2) TranS1 knowingly offered and paid illegal remuneration to certain physician providers for participating in speaker programs and consultant meetings in a manner intended to induce them to use TranS1 products in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b); and (3) TranS1 knowingly promoted the sale and use of axial lumbar interbody fusion devices for uses that were not approved or cleared by FDA, including in certain spine procedures involving complex deformity affecting vertebral levels other than the levels for which AxiaLIF is FDA-cleared. Some of these uses were not reasonable and necessary for the diagnosis or treatment of an illness or injury, contrary to 42 U.S.C. § 1395y(a)(I)(A), and thus were not covered by Medicare, Medicaid, or the Other Federal Health Care Programs.

The Settlement Amount represents an outsize 28% of the Company's reported cash and short term investments.

12. Throughout the Class Period, Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (1) Defendants engaged in a scheme to encourage surgeons to continue using the CPT code for anterior procedures in direct disregard of the AMA's Category III code assignment for AxiaLIF; (2) the Company's revenues, derived primarily from sales of AxiaLIF as well as a portion of the insurance reimbursement each performing provider received as a result of using improper billing codes for AxiaLIF, were generated as a direct result of Defendants' improper coding scheme; (3) the Company was in violation of the Federal False Claims Act, North Carolina False Claims Act and other federal healthcare fraud statutes; (4) the Company's improper

reimbursement practices rendered it highly likely that it would face regulatory scrutiny; (5) the Company lacked adequate internal and financial controls; and (6) as a result of the foregoing, the Company's statements were materially false and misleading at all relevant times.

13. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

14. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder (17 C.F.R. §240.10b-5).

15. This Court has jurisdiction over the subject matter of this action pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1331.

16. Venue is proper in this District pursuant to §27 of the Exchange Act, 15 U.S.C. §78aa and 28 U.S.C. §1391(b) as Trans1's principal place of business is located within this District.

17. In connection with the acts, conduct and other wrongs alleged in this Complaint, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

PARTIES

18. Lead Plaintiff, as set forth in his Certification previously filed with this Court, purchased Trans1 securities at artificially inflated prices during the Class Period and has been damaged thereby.

19. Defendant Trans1 is a Delaware corporation, with its principal place of business located at 301 Government Center Drive, Wilmington, N.C. 28403. Trans1's common stock trades on the NASDAQ Global Market ("NASDAQ") under the ticker symbol "TSON." The Company sells its products directly to hospitals and surgical centers in the United States and certain European countries, and to independent distributors elsewhere.

20. Defendant Kenneth Reali ("Reali") has been the Company's Chief Executive Officer ("CEO") and a director on the Board of Directors ("Board") since January 4, 2011 and President since January 2010. Defendant Reali served as the Company's Chief Operating Officer from January 4, 2010 through January 2011.

21. Defendant Joseph Slattery ("Slattery") has been the Company's Executive Vice President and Chief Financial Officer ("CFO") since April 2010. Defendant Slattery served as a director on the Board from November 2007 through April 2010.

22. Defendant Richard Randall ("Randall") served as the Company's Chief Executive Officer from June 2002 to January 2011, and served as its President from June 2002 until January 2010. Defendant Randall has been a member on the Company's Board since June 2002 and has served as the Company's Executive Chairman of the Board since January 4, 2011. During the Class Period, between May 26, 2010 and May 27, 2010, Defendant Randall disposed of a massive 100,000 shares of Company stock at inflated prices. He sold an additional 20,000 shares of stock at inflated prices on August 17, 2011, a mere two months before the end of the Class Period.

23. Defendant Michael Luetkemeyer ("Luetkemeyer") served as the Company's Chief Financial Officer from April 2007 through March 2010.

24. The defendants referenced above in ¶¶ 18 through 21 are sometimes referred to herein as the "Individual Defendants."

SUBSTANTIVE ALLEGATIONS

Background

25. Trans1 is a medical device company focused on designing, developing and marketing products that implement its minimally invasive surgical approach to treat degenerative conditions of the spine affecting the lower lumbar region. The Company currently markets the AxiaLIF ® family of products, ***which is its primary source of revenue***.

26. AxiaLIF utilizes a "pre-sacral" approach designed to provide the least invasive means for surgeons to perform fusion and motion preserving surgeries in the L4/L5/S1 region of the spine as compared to the current alternative lumbar fusion procedures. The AxiaLIF procedure is performed straight up the tailbone, rather than through the anterior (front) portion of the spine. In other words, as explained in the Company's own filings, the patient is on his/her stomach for the entire procedure, rendering the procedure distinct from traditional fusion surgeries which utilize an "anterior", or frontal, approach.

27. The Company received 510(k) clearance from the FDA for AxiaLIF 1L in the fourth quarter of 2004, and commercially introduced its AxiaLIF 1L product in the United States in the first quarter of 2005. It received FDA 510(k) clearance for AxiaLIF 2L and began marketing this product in the United States in the second quarter of 2008. The AxiaLIF 2L product was discontinued in 2010 after Trans1 launched the AxiaLIF 2L+™ product in July 2010, for which it received FDA 510(k) clearance in January 2010. The FDA's 510(k) approval process, through which all of the Company's products were marketed, is far less costly and rigorous than the FDA's Pre-Market Approval process for a device or pharmaceutical, and ***requires less supporting clinical data***. As a result, the Company did not have substantial long-term clinical data supporting the safety and efficacy of its AxiaLIF products.

28. While the 510(k) process made it easier, and quicker, for the Company to obtain FDA approval, it resulted in a dearth of evidence to evaluate whether AxiaLIF is as effective or as safe as other surgical approaches to lumbosacral interbody fusion. This was especially true in light of the fact that the AxiaLIF procedure, unlike other fusion surgeries which have been adequately tested and studied, does not employ an anterior approach but rather is solely performed straight up the tailbone. It is this lack of evidence, as well as its unique procedure, which ultimately led the AMA to consider AxiaLIF "investigational" or "experimental."

The AMA Issues a Category III Code for AxiaLIF

29. In order to facilitate reimbursement to doctors for services rendered, the AMA developed a system of CPT codes, divided into three categories, which is utilized by insurance companies and federally funded insurance programs to determine eligibility and levels of reimbursement. Federal law, including the False Claims Act, requires surgeons to label services rendered with an appropriate CPT code, to insure that reimbursement from these sources are legitimately procured. Thus, to submit a claim for reimbursement for the AxiaLIF procedure to insurance companies, surgeons must utilize the proper CPT code. Prior to 2009, AxiaLIF could be coded in one of three ways: a) as an anterior fusion procedure, b) as a posterior fusion procedure, or c) as a lateral fusion procedure. Trans1 identified AxiaLIF as an anterior fusion procedure and the surgeons generally coded it accordingly. When coded as an anterior fusion procedure, surgeons had no problem obtaining reimbursement for AxiaLIF, insuring a consistent revenue stream for the Company.

30. However, in February 2008, the National Association of Spine Surgeons Reimbursement Coding Committee, which is charged to monitor new procedures and devices and there reimbursement, proposed a Category III CPT code for the AxiaLIF procedure to the AMA.

Category III coding is typically applied when there is a lack of clinical data regarding a device which renders it a "new and emerging" technology. Indeed, because Defendants obtained approval for AxiaLIF using the 510(k) process, it suffered from a dearth of safety and efficacy data. In addition, the AxiaLIF procedure did not employ an anterior (frontal) approach like many other traditional fusion surgeries, and thus could not be sufficiently compared to such surgeries to assure safety and efficacy. Due to the scarcity of supportive data and the uniqueness of the AxiaLIF procedure, the AMA assigned a Category III CPT code 0195T to the device, effective January 1, 2009. The assignment of a Category III, or "T Code" to AxiaLIF identified the procedure as "investigative" or "experimental" to insurance companies. In light of this designation, most insurance companies (including federally funded programs) refused to reimburse surgeons for the procedure, thereby threatening the Company's revenue stream and financial viability.

Defendants Encourage Physicians to Engage in Improper Reimbursement Tactics

31. Desperate to maintain its primary source of income, Defendants embarked upon an extensive scheme to convince surgeons to engage in improper reimbursement practices in direct violation of the False Claims Act, North Carolina False Claims Act, and other federal healthcare statutes. Specifically, Defendants encouraged and coached surgeons to utilize alternate codes, instead of the mandated experimental Category III designation assigned to AxiaLIF, in order to allow for reimbursement for the procedure.

32. To execute this scheme, Defendants formed a reimbursement committee, headed by Amy Conners, for the sole purpose of training surgeons to avoid the mandatory Code III designation. At Defendants' direction, Conners and her team drafted presentations for surgeons detailing exactly which non-experimental codes to use, and in what manner, so that insurance

companies would reimburse them for the AxiaLIF procedure. Conners also created a hotline to which surgeons could call for tips on how to code the procedure and avoid the Category III code.

33. Trans1 also held periodic conference calls on which distributors were coached to tell surgeons to use the Category I CPT code intended for anterior fusion procedures, a non-experimental code, even though the AMA required them to use the experimental 0195T Category III code. Aside from the fact that such instructions clearly violated the AMA's Category III designation, AxiaLIF clearly did not qualify as an anterior procedure, because: 1) it is performed straight up the tailbone and never approaches the anterior portion of the spine; and 2) the device is inserted through the back with patient lying on his stomach throughout the entire procedure. To assuage nervous doctors who were aware of the Category III designation, distributors were advised to tell surgeons that this is how all surgeons coded for the procedure.

Trans1's Suspicious "Training Sessions"

34. In a further attempt to encourage doctors to manipulate their reimbursement coding, Trans1 held on site training sessions for surgeons at locations where they knew the physicians were utilizing improper coding for AxiaLIF, such as the code for anterior fusion procedures, as opposed to the proper Category III code. The most popular of these training sites was in Cincinnati, Ohio where Dr. William Tobler conducted training sessions. Dr. Tobler, Trans1's top consultant, conducted frequent training sessions and gave numerous presentations during the Class Period promoting the Company's AxiaLIF procedure. At those training sessions, Dr. Tobler coded for the AxiaLIF procedure as a Category I procedure. These training sessions were crafted to create the optimal environment for surgeons to share tips on how to manipulate the coding to get reimbursed.

The Illicit "Reimbursement Guide" and "Template"

35. Defendants also developed and distributed to surgeons a "Reimbursement Guide," dated January 1, 2009 through June 30, 2009. The Reimbursement Guide enumerates multiple codes which it states "may be appropriate during an AxiaLIF procedure", the overwhelming majority of which are not the mandated Category III code. It is only on the last page of the guide that physicians learn that in fact AxiaLIF had been assigned a Category III CPT billing code. The Reimbursement Guide acknowledges that payors may deny claims submitted under the Category III CPT code and brazenly directs physicians to use alternate codes to secure reimbursement.

36. Going even further in their effort to encourage surgeons to break the law, the Company directed Dr. Tobler to create a reimbursement template that discussed precisely how to code AxiaLIF as an anterior procedure to enable reimbursement. The template went so far as to suggest post operation notes to disguise the fact that the procedure was an AxiaLIF procedure, which might trigger the denial of a reimbursement claim.

37. Moreover, during the Class Period, Trans1 held annual National Meetings, attended by the Company's employees and executives. At the 2009 meeting, which Defendant Randall attended, the Company continued to promote the use of the anterior CPT code, despite the fact that the Category III code had already been assigned to AxiaLIF.

38. As a result of these machinations, all of which were undisclosed to investors, the Company violated the False Claims Act, North Carolina False Claims Act, as well as other federal anti-fraud and healthcare statutes. Indeed, Defendants' blatant gamesmanship created an acute risk that the Company would be subject to legal action as well as scrutiny by the DHHS and other regulatory bodies.

The Qui Tam Complaint

39. On April 21, 2011, plaintiff and *qui tam* Relator Kevin J. Ryan, who was employed by TranS 1 Inc. from approximately July 1, 2008 to January 18, 2010 as a Clinical Sales Manager, filed suit[3] against Trans1 alleging that the Company "submitted and facilitated the submission of false and fraudulent claims, statements and/or documents to federal agencies by causing physicians and hospitals to submit improper claims for payment to Medicare and state health insurance programs and insurers." ¶ 2. The Complaint alleges that "the Federal Treasury and the State of North Carolina have been damaged in a substantial amount that is yet to be determined, currently estimated at approximately $20,000,000.00." ¶ 3.

40. The qui tam Complaint alleges that Defendants, by promoting use of improper CPT codes to bill for AxiaLIF, misrepresented to physicians and hospitals that the FDA had approved AxiaLIF as similar to reimbursable "anterior stabilization and fusion procedures" without clarifying that it must be performed as an "adjunct to posterior fusion and instrumentation", which would not be reimbursed by insurers. ¶ 49.

41. The qui tam Complaint makes clear that Defendants designed their sales training process and marketing to promote AxiaLIF for off-label use by encouraging use of billing codes reserved for reimbursable spinal devices and procedures instead of using the experimental T-Code assigned to AxiaLIF. ¶¶ 61-63.

42. The qui tam Complaint demonstrates that Defendants were well aware of and indeed discussed the threat to marketing and profitability posed by the non-reimbursable status of the experimental T-code. ¶ 64. Nevertheless, Defendants proceeded to promote off-label use of AxiaLIF and improper billing techniques to secure reimbursement. ¶ 66.

[3] *United States ex reI. Ryan v. TranS1, Inc.*, 1:11-cv-01041-MJG (D. Md. 2011)

43. Since 2009, Defendants coached hospitals and physicians to omit all references to the T-Code assignment and to instead improperly code AxiaLIF as one of the Medicare reimbursable anterior and/or posterior interbody fusion procedures. Hospitals and physicians were coached to mask the "adjunct to fusion" indication within the spinal procedure as a whole so as to obtain improper reimbursement. Providers were further coached not to make reference to "Trans1" "so as not to raise red flags about the reimbursability of the services." Indeed, Rick Simmons, Trans1's Vice President of Marketing and Sales, told Relator, after learning that a provider used Trans1's name and was denied preauthorization, that "trade names are taboo ... anterior stabilization and fusion are more *[sic]* better." Trans1 employees gave hospitals sample post op notes and billing templates for use to obtain reimbursement. Hospitals were often not even made aware that AxiaLIF had been assigned an experimental T-Code. Providers who had received a denial of coverage were directed to Amy Connor, Trans1's reimbursement specialist, for instructions on how to get reimbursed. These instructions were also "taught" to sale representatives at the Company's various national sales meetings. Specifically, sales representatives were coached to tell physicians to use the 22899 CPT code and bill AxiaLIF as an Anterior Lumbar Interbody Fusion rather than the correct 0195 T-Code issued to AxiaLIF. ¶¶ 67-92; 98-101.

44. The qui tam Complaint alleges specific examples that illustrate Defendants' improper reimbursement scheme, including: 1) Upon coaching surgeons at a Boston hospital on how to improperly code for AxiaLIF, the hospital told Trans1 sales representative Patrick Caylor that it was illegal to bill for AxiaLIF that way and that it would not follow his improper instructions. ¶ 88; 2) In a phone conversation with a client surgeon regarding Trans1's instruction that AxiaLIF be billed as an anterior fusion procedure, the surgeon responded "If I use any other

code other than the T-Code that would be [Medicare] fraud"; 3) On February 27, 2009, Dr. Gary Cram of Carolina Neurosurgery P.A. in Greensboro, NC performed an AxiaLIF procedure on patient G.P. which he billed using CPT Code 22899, instead of 0195T or 0196T, at the instruction of Trans1 and received $1,252 in improper reimbursement. ¶ 98. For that same patient in the same procedure, Dr. Randy Kritzer also submitted and was successfully reimbursed $5,010 using CPT Code 22899 instead of the proper unreimbursable T –Code, also at Trans1's instruction. ¶ 99; 4) Carolina Neurosurgery P.A. also received reimbursement for another AxiaLIF procedure performed on patient H.H. by Dr. Randy Kritzer and Dr. David Jones in the amount of $6,262 using CPT Code 22899, instead of as 0195T, per Trans1's instruction. ¶ 100; and 4) Triangle Neurosurgery P.A. of North Carolina obtained reimbursement for AxiaLIF at Trans1's instruction, by coding for the main procedure as 22558 (anterior lumbar interbody fusion) and 22851 (anterior instrumentation) receiving a combined payment of $4,461.81. ¶ 101.

45. The qui tam Complaint drew the attention of regulators who, as discussed below, issued a subpoena six months later to Trans1 seeking, among other things, patient names to serial lot traceability to reimbursement communications with physicians.

46. As mentioned above, the $6 million Settlement Agreement with the government, effective June 28, 2013, also settles the Relator's claims set forth in the qui tam Complaint.

Confidential Witnesses

47. Several former Trans1 employees have also confirmed Defendants' systematic attempt to convince surgeons to submit improper reimbursement requests to insurance companies and federally funded healthcare programs.

48. Confidential Witness 1 ("CW1"), a former product manager at Trans1 from August 2007 until April 2010, stated that when he first joined Trans1 in 2007, the insurance companies

had not assigned a specific CPT code for Trans1's AxiaLIF procedure. As such, doctors used a series of "general" codes to obtain reimbursement for the procedure. CW1 explained that there were 3 possible codes for a spinal fusion procedure available before Trans1 was assigned the experimental T-code in January 2009: a) an ALIF or anterior lumbar interbody fusion; b) a PLIF, or posterior lumbar interbody fusion or c) a TLIF, a transforaminal lumbar interbody fusion. According to CW1, Trans1 coded its AxiaLIF procedure as an ALIF procedure. However, CW1 explained that although the procedure was coded as an ALIF procedure, it did not truly meet the requirements for this code because access to the spine was achieved through the posterior region of the body, not the anterior. According to CW1, an ALIF procedure is supposed to go through the patient's stomach.

49. CW1 stated that Trans1 received an "experimental" code in January 2009, which caused insurance companies to cease reimbursing surgeons for the AxiaLIF procedure. According to CW1, because Trans1's code was designated "experimental," the new code served as a red flag to insurance companies to deny coverage of the procedure. CW1 said that NAS recommended that AMA assign an experimental T-code to the AxiaLIF procedure. CW1 said that surgeons did not gravitate toward using the AxiaLIF procedure because it was "different" and was not the "standard of care."

50. CW1 further stated that Amy Conner (the former head of reimbursement) told him that she warned the Vice President of Sales, Rick Simmons, in the fall of 2008 that if Trans1 received the new Category III "experimental" T-code, it would have a very negative impact on sales.

51. From conversations with Conner and other colleagues, CW1 learned that after the implementation of the new code in January 2009, "doctors were being coached on how to code it

so they could bury the [newly designated] code" and get the procedure reimbursed. According to CW1, at the direction of senior management, Conner gave presentations to surgeons showing them how to code the procedure in order to get reimbursed. CW1 explained that during these presentations, Conner showed how surgeons typically coded a general spinal fusion procedure using other companies' products. Then she demonstrated how to code it using Trans1's AxiaLIF's device. CW1 observed Conner showing surgeons how to input the numbers in a certain order to ensure reimbursement for the procedure. CW1 said that Conner's presentations focused on showing surgeons how to bury the new T-Code in the bottom part of the reimbursement request so that insurance companies might overlook it. According to CW1, Conner also made presentations to the Trans1's Board regarding reimbursement issues. In addition, Trans1 set up a "hotline," staffed with Conner's people, that doctors could call to get their questions answered regarding coding.

52. Confidential Witness 2 ("CW2") was the clinical data manager in the research division of Trans1, from May 2008 until he was laid off in April 2011. He reported to the director of clinical operations. CW2 was hired to build an electronic database for Trans1 clinical trials, and his job included verifying research documents and ensuring that clinical data was properly prepared and entered into a database. According to CW2, from 2005 to 2009, insurance companies covered the AxiaLIF procedure as "an anterior procedure." According to CW2, the NAS decided in 2008 that Trans1's procedure was "not a traditional anterior procedure." The AMA, which considered the NAS the experts in the field, followed its decision and assigned an "exploratory" code to the AxiaLIF procedure effective January 2009. CW2 explained that during a review of many non-traditional minimally invasive surgeries, the NAS made this decision because the point

of entry for the AxiaLIF procedure is straight up the tailbone, instead of through the anterior portion of the spine.

53. CW2 stated that the code change led to financial difficulties for the Company because most insurance companies no longer covered the AxiaLIF procedure, and fewer doctors used it due to concerns about reimbursement. "It's a very competitive market and there are multiple solutions" for surgeons to utilize in treating back problems, CW2 said. "If one procedure has a blight on it, they won't use it. If there are financial difficulties they won't use it."

54. According to CW2, shortly after the AMA announced the code change, Trans1 formed a reimbursement group to "coach" physicians on how to code the AxiaLIF procedure to get reimbursed for AxiaLIF. In fact, as CW1 explains, after the new "T-code" was assigned, Conner (former head of reimbursement) gave PowerPoint presentations to surgeons, which CW1 attended, showing them how to code the AxiaLIF procedure by burying the new code lower on the list so that they would get reimbursed.

55. Confidential Witness 3 ("CW3") was a distributor of Trans1 and other spinal products since December 2006. He began distributing Trans1's AxiaLIF in 2008. According to CW3, there were always coding and reimbursement issues with AxiaLIF because it did not utilize a "traditional approach." CW3 stated that in 2009 at the National Society of Spine Surgeons conference in Las Vegas, Nevada, Dr. Will Smith was scheduled to speak about the AxiaLIF procedure. Smith, who had done more AxiaLIF procedures than any other surgeon in the country, and had helped found the Company, gave a scathing review of AxiaLIF at the conference. Smith reported poor success rates, infections, and cases where the implants did not fuse to the spine. As a result of this speech, CW3 said that surgeons avoided AxiaLIF "like the plague" and Trans1 never got the Category I code it needed to ensure reimbursement for the procedure.

56. According to CW3, Trans1 had a coding department which held periodic conference calls with distributors about coding and told distributors what to tell surgeons about coding. Trans1 told distributors to use an "ALIF" code, despite the fact that it did not qualify as an anterior procedure. CW3 explained that if the implant does not end up in the anterior third of the vertebral body during the procedure, the surgeon cannot claim he has performed an anterior procedure and use the ALIF code. AxiaLIF did not end up in the anterior third of the spine so it did not qualify as an anterior procedure.

57. According to CW3, distributors were told to tell surgeons to "flip the patient over" and do anterior and posterior fusion (also known as a 360). According to CW3, Trans1 advised distributors that if some surgeons were not comfortable and did not want to be "seen as coding something that is not there," distributors were supposed to tell them: "We have seen other surgeons use this code and be successful." As a result of all these code changes, Trans1 lost credibility with surgeons, who thought using some of the Company's code suggestions were unethical. According to CW3, "Trans1 told us to do whatever we had to do," to get surgeons to use its product. He recalled after another call he was told to suggest a T-LIF code.

58. As CW3 stated, "[AxiaLIF] was doomed to fail without its own code." CW3 stopped selling its products in April 2011 because Trans1 "sold a lot of lies and hurt a lot of people…I felt they were asking me to say stuff that was not true."

59. Confidential Witness 4 ("CW4"), a regional sales manager for Trans1 from January 2011 until he was laid off in February 2012, explained that when the AxiaLIF procedure is performed, the patient is always placed face down on the table. The tables are specially constructed to enable the patient to be in a prone position on their knees with their buttocks in the air and their face on the table. The incision is made about 2 inches north of the rectum and the device is

implanted along the lower portion of the spine. According to CW4, at no point is the patient flipped over. In other words, use of the anterior procedure coding was wholly inappropriate, because the device never passed through the stomach, and was not implanted in the anterior third of the spine.

60. According to CW4, when he started working at Trans1, it was already using the new T-Code for reimbursement. CW4 said the T-Code was categorized as an "investigational" code, and as a result, surgeons who tried to use it did not get reimbursed for the procedure from insurance companies. As a result, CW4 says he "didn't have any business…because the doctors couldn't get paid." He explained that none of the physicians he called wanted to use the T-code and not get reimbursed for the procedure. CW4 explained that, "the only way to get paid for it was for the doctor to do something shifty."

61. Confidential Witness 5 ("CW5") worked as a District Sales Manager at Trans1 covering four mid-Western states from March 2008 until January 2010 and as Regional Sales Manager for 10 mid-Western states from around October 2011 until he was laid off on May 31, 2012. CW5 explained that he was laid off because Trans1 couldn't get any business since it did not have the right code to get reimbursed for the AxiaLIF procedure. According to CW5, until January 2009, Trans1 had not yet received a separate "T-Code" for its AxiaLIF procedure. As a result it could be coded in one of three ways: a) as an anterior fusion procedure, b) as a posterior fusion procedure, or c) as a lateral fusion procedure. According to CW5, Trans1 coded it as an anterior fusion procedure and surgeons had no problem getting reimbursement from insurance companies. CW5 said that "All the surgeons I worked with coded it that way" because it "was the only code available to use." Once the new CPT code came out in January 2009, however, Trans1 continued to encourage surgeons to code the procedure as an anterior fusion procedure in order to continue to get reimbursed. CW5 stated that "When we got the T-code, surgeons couldn't get it

approved, so they had to use another approach…There were still some backdoor … 'hey just code it as an anterior and it'll get reimbursed.'"

62. CW5 explained that Trans1 routinely sent prospective surgeons and its sales reps to participate in onsite training where surgeons performed the AxiaLIF procedure on cadavers. According to CW5, Trans1 made sure to schedule the onsite visits at places that were using the anterior coding, despite the T-code assignment, and the fact that AxiaLIF was clearly not an anterior procedure. CW5 explained: "We were definitely instructed to tell them to code it as an anterior procedure**.**" According to CW5, A lot of onsite visits took place in Cincinnati, Ohio, where the procedure was performed by a surgeon named Dr. William Tobler. CW5 said the training visits were set up so that the surgeons could talk amongst themselves about anything involving the procedure, including coding.

63. According CW5, Dr. Tobler created a template that discussed exactly how to code the procedure as an anterior procedure so that the surgeons could get reimbursed. CW5 stated that the template even contained suggested post-operation notes so the insurance companies would not view the procedure as an AxiaLIF procedure and deny reimbursement. According to CW5, he was instructed to tell surgeons: "I can't give you direct advice on how to code, but here is what I've heard other people are doing."

64. CW5 attended regular Regional Sales Managers Meetings and National Meetings for Trans1 which occurred at least once a year. At the 2008 National Meeting in Las Vegas, Nevada, Trans1 was still using the "anterior" code for the AxiaLIF procedure and sales were strong. According to CW5, at the National Meeting in January 2009 held in Nevada, Trans1 was still promoting use of the anterior coding for the AxiaLIF procedure, despite the fact that the AMA had already assigned it a Category III code. CW5 said the official company line was to tell

surgeons, “We have a T-code, but here’s how other guys are coding it.” Defendant Randall attended these meetings.

65. Indeed, CW5 stated that he heard from the former Regional Sales Manager in North Carolina that Dwayne Montgomery, Vice President of Sales, instructed him to tell surgeons to inappropriately code the procedure. The former Regional Sales Manager refused and lost his job as a result.

66. Confidential Witness 6 (“CW6”) was the international marketing coordinator for Trans1 from December 2007 to February 2011 when she was laid off. During that time, CW6 reported to the vice president of international sales. CW6 also worked as an administrative assistant to Defendants Randall and Reali until April 2010. According to CW6, when she first joined Trans1, doctors received reimbursement for the AxiaLIF procedure and it was not considered experimental. After AxiaLIF received the Category III code in January 2009, the new code “red flagged” the procedure as “experimental.” Up until that point, Trans1 had been gaining market share. CW6 described the new code as “pretty devastating to the bottom line.” According to CW6, surgeons “won’t do the procedure if they’re not paid.”

67. Confidential Witness 7 (“CW7”), a former South East sales manager for Roundtable Medical from April 2008 until November 2011, was the largest Trans 1 distributor in South Florida. CW7 worked with doctors already using AxiaLIF rather than selling to new accounts. According to CW7, there were reimbursement issues with Trans1’s AxiaLIF fusion system, and “a lot of accounts stopped using us.” CW7 stated that after AxiaLIF received the new coding, providers became unsure they would be reimbursed for the AxiaLIF procedure and “business literally went from great to nothing.”

68. CW7 explained that prior to 2009, surgeons often used a 360 code to obtain reimbursement for AxiaLIF, a code used for an anterior and posterior fusion. In this procedure, "you lay the patient on their back, put the device in from the front, flip the patient over and put the screws in the back." The 360 was "the highest reimbursement code." According to CW7, at some point in time the AMA assigned a "T-code", generally used for experimental procedures. CW7 learned that the 360 code should never have been used in the first place. Doctors began to steer clear of the AxiaLIF procedure because of the reimbursement confusion. CW7 stated that "we were always trying to figure out what code to tell doctors to use." Both doctors and hospitals were worried about reimbursement for the AxiaLIF system.

Materially False and Misleading
Statements Issued During the Class Period

69. On February 23, 2009, Trans1 held an analyst earnings call for the fourth quarter of 2008. On that call, Defendants Randall and Luetkemeyer spoke about the migration to Category III coding, which when used, would prevent surgeons from receiving reimbursement for the AxiaLIF procedure. Specifically, the Defendants stated in relevant part:

> Defendant Randall: On the reimbursement front, we remain diligent about helping our surgeons obtain appropriate reimbursement for our procedure. We have an 800 number and a call-in resource center up and running to assist surgeons with reimbursement issues that may arise.
>
> As many of you know, a portion of our surgeon fee migrated from an unlisted code to a category three CPT tracking code in January 2009. While we remain focused on supporting our surgeons through this transition, we do not anticipate that this will create any significant additional headwind with regards to adoption.
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> Defendant Luetkemeyer: Doug, what we said in the script was that the conversion from unlisted to category three, we didn't see giving us any significant additional headwind. I think the metric that we've provided in the past is that we feel, and it's hard to really quantify it, but we feel that unlisted code gave us about a 5% kind of a headwind and it's probably consistent again this year. We don't feel that moving

> from unlisted to category three is going to provide any significant additional headwind.

70. On March 13, 2009, the Company filed an annual report for the period ended December 31, 2008 on Form 10-K with the SEC, which was signed by, among others, Defendants Randall, Luetkemeyer and Slattery, and reiterated the Company's previously announced annual financial results and financial position. In addition, the Form 10-K contained signed certifications by Defendants Randall and Luetkemeyer, stating that the financial information contained in the Form 10-K was accurate and that they disclosed any material changes to the Company's internal control over financial reporting.

71. The 10-K represented the following:

> Our revenue is derived entirely from sales of our AxiaLIF products and related surgical instruments. We expect that sales of our AxiaLIF products will continue to account for a substantial portion of our revenues for the foreseeable future.
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> Surgeons use the American Medical Association's Current Procedural Terminology, or CPT, system to bill payors for the AxiaLIF procedure. CPT codes describe the services and procedures provided for patients to third party payors so that physicians may be reimbursed. Effective January 1, 2009, AxiaLIF has a dedicated Category III CPT code (0195T-arthrodesis, presacral interbody technique, including instrumentation). Unlike Category I CPT codes, Category III codes do not have a set value which physicians use to set their charge for a particular code. Additionally, some payors view Category III codes as "investigational" or "experimental" and may not reimburse them. However, AxiaLIF adoption continues to grow and unlike many new or novel procedures, AxiaLIF is an access variation on the current standard of care (spinal fusion). As the availability of peer-reviewed research continues to grow, we will diligently work with the private payor community to ensure continued patient access to the procedure. Furthermore, AxiaLIF is only one of up to 10 different CPT codes physicians may submit to capture the entirety of a spinal fusion procedure lessening the impact should payment for our code be initially denied.

72. The foregoing statements were false and/or misleading because they failed to disclose to investors that: (1) Defendants engaged in a scheme to encourage surgeons to employ

CPT codes meant for anterior and other non-Category III procedures in direct disregard of the AMA mandated Category III code for AxiaLIF; (2) a substantial portion of the Company's earnings and revenues were thereby earned as a result of violations of the Federal False Claims Act, North Carolina False Claims Act and other healthcare fraud statutes; and (3) as a result of the Company's practices, there was a substantial risk that Trans1 would encounter regulatory scrutiny.

73. On April 27, 2009, the Company issued a press release announcing its financial results for the first quarter ended March 31, 2009. For the quarter, the Company reported a net loss of $5 million, or $0.25 diluted LPS and revenue of $9 million, as compared to a net loss of $2 million, or $0.12 diluted LPS and revenue of $6 million for the same period a year ago.

74. On a conference call that same day, Defendant Randall updated investors regarding reimbursement and coding issues. Defendant Randall stated in relevant part:

> On the reimbursement front, we remain diligent about helping our surgeons obtain appropriate reimbursement for our procedure. We have an 800 number and call-in resource center, up and running to assist surgeons with reimbursement issues that may arise.
>
> We have also added two additional reimbursement specialists in the field to work with our surgeon customers and their billing specialists, to help them determine the appropriate coding for the fusion procedures they are performing.
>
> As a strong case volume this quarter would suggest, we have not seen a drop off in procedure volumes as a result of the current weak economic conditions. Having said that, we have begun to see some insurance companies raising the bar on whether to pay for fusion surgery in general or asking more patients to get a second opinion, before agreeing to cover the procedure.
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> …we had the category-three code put in place in January and that was a change in coding. We have actually put out a coding guide now, which has been blessed by everyone. And coding fusions is fairly complex and what we saw initially with the category-three code was right away a lot of coders in the practice went to the concern that like the Charité disc they are just not going to get paid.

> The reality is, as we've discussed in the past, this access code is one of several codes that they employ during a typical fusion. So I would say our coding issues have been grassfires, not forest fires, and so, this flare is up. A coder becomes concerned, because they see a category-three code. And we either work through the rep, or we work through the hotline, or now we've actually, as I have mentioned, brought on a couple of field related personnel, who had worked by the way at Saint Francis Medical, where they knew category-three code inside and out. Those people are then, if needed, deployed and we put these fires out.
>
> I don't think we've had many instances, if any, where we just have surgeons stop doing this, but often times there is a concern when they see the category-three code. We need to work with them and once they understand the coding sequence, based on the particular operation that that surgeon does, we move through the process. So, that's why we proactively hired these folks. And now, the plan going forward is as we bring in new surgeon on by having field base, personnel to deal with this matter. We can actually have those personnel meet with the coders before the surgeon even treats patients with AxiaLIF, so that we don't even have the little flash fire to deal with.

75. On May 6, 2009, the Company filed a quarterly report for the period ended March 31, 2009 on Form 10-Q with the SEC, which was signed by Defendants Randall and Luetkemeyer and reiterated the Company's previously announced quarterly financial results and financial position. In addition, the Form 10-Q contained signed certifications by Defendants Randall and Luetkemeyer, stating that the financial information contained in the Form 10-Q was accurate and that they disclosed any material changes to the Company's internal control over financial reporting.

76. The foregoing statements were materially false and misleading for the reasons set forth in ¶ 71.

77. On July 31, 2009, the Company issued a press release announcing its financial results for the second quarter ended June 30, 2009. For the quarter, the Company reported a net loss of $7 million, or $0.33 diluted LPS and revenue of $8 million, as compared to a net loss of $5 million, or $0.26 diluted LPS and revenue of $6 million for the same period a year ago.

78. On August 6, 2009, the Company filed a quarterly report for the period ended June 30, 2009 on Form 10-Q with the SEC, which was signed by Defendants Randall and Luetkemeyer and reiterated the Company's previously announced quarterly financial results and financial position. In addition, the Form 10-Q contained signed certifications by Defendants Randall and Luetkemeyer, stating that the financial information contained in the Form 10-Q was accurate and that they disclosed any material changes to the Company's internal control over financial reporting.

79. The foregoing statements were materially false and misleading for the reasons set forth in ¶ 71.

80. On October 29, 2009, the Company issued a press release announcing its financial results for the third quarter ended September 30, 2009. For the quarter, the Company reported a net loss of $5.6 million, or $0.27 diluted LPS and revenue of $7 million, as compared to a net loss of $5 million, or $0.23 diluted LPS and revenue of $6 million for the same period a year ago.

81. On November 6, 2009, the Company filed a quarterly report for the period ended September 30, 2009 on Form 10-Q with the SEC, which was signed by Defendants Randall and Luetkemeyer and reiterated the Company's previously announced quarterly financial results and financial position. In addition, the Form 10-Q contained signed certifications by Defendants Randall and Luetkemeyer, stating that the financial information contained in the Form 10-Q was accurate and that they disclosed any material changes to the Company's internal control over financial reporting. The 10-Q stated in relevant part:

> Revenue. Revenue increased from $6.0 million in the three months ended September 30, 2008 to $6.9 million in the three months ended September 30, 2009. The $0.9 million increase in revenue from 2008 to 2009 was primarily attributable to an increase in the number of AxiaLIF products sold, which we believe resulted from continued market acceptance of our AxiaLIF and AxiaLIF 360° products, and the commercialization of our AxiaLIF 2L product in the United States, which had

> its full market release in the fourth quarter of 2008. Our revenues this quarter were impacted by continuing uncertainty in the marketplace surrounding reimbursement for our AxiaLIF procedure, which we are addressing with increased education and support resources for our current and prospective surgeon users. None of this increase was attributable to price increases.

82. The foregoing statements were materially false and misleading for the reasons set forth in ¶ 71.

83. On February 23, 2010, the Company issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2009. For the fourth quarter, the Company reported a net loss of $5.7 million, or ($0.28) diluted LPS and revenue of $6 million, as compared to a net loss of $4.5 million, or ($0.22) diluted LPS and revenue of $7.35 million for the same period a year ago. For the year, the Company reported a net loss of $23 million or ($1.13) diluted LPS and revenue of $30 million, as compared to a net loss of $17 million, or ($0.84) diluted LPS and revenue of $25 million for the same period a year ago.

84. On March 12, 2010, the Company filed an annual report for the period ended December 31, 2009 on Form 10-K with the SEC, which was signed by, among others, Defendants Randall, Luetkemeyer and Slattery, and reiterated the Company's previously announced annual financial results and financial position. In addition, the Form 10-K contained signed certifications by Defendants Randall and Luetkemeyer, stating that the financial information contained in the Form 10-K was accurate and that they disclosed any material changes to the Company's internal control over financial reporting.

85. The 10-K represented the following:

> Our revenue is derived entirely from sales of our AxiaLIF products and related surgical instruments. We expect that sales of our AxiaLIF products will continue to account for a substantial portion of our revenues for the foreseeable future.

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> Surgeons use the American Medical Association's Current Procedural Terminology, or CPT, system to bill payors for the AxiaLIF procedure. CPT codes describe the services and procedures provided for patients to third party payors so that physicians may be reimbursed. Effective January 1, 2009, the AMA implemented a Category III code which may describe the work involved in treating some AxiaLIF patients. Unlike Category I CPT codes, Category III codes do not have a set value which physicians use as a benchmark for setting their fee. Additionally, some payors view Category III codes as "investigational" or "experimental" and may not reimburse them. However, AxiaLIF adoption continues to grow and unlike many new or novel procedures, AxiaLIF is an access variation on the current standard of care (spinal fusion) and surgeons should code appropriately for the work they perform based on the unique clinical decision making, time, risk, and diagnosis of each patient.

86. The foregoing statements were materially false and misleading for the reasons set forth in ¶ 71.

87. On May 4, 2010, the Company issued a press release announcing its financial results for the first quarter ended March 31, 2010. For the quarter, the Company reported a net loss of $6 million, or $0.31 diluted LPS and revenue of $6.7 million, as compared to a net loss of $5 million, or $0.25 diluted LPS and revenue of $8.7 million for the same period a year ago.

88. That same day, the Company held a conference call with analysts. On that call, Defendants Slattery and Reali stated in relevant part:

> Defendant Slattery: Revenues in the first quarter of 2010 were $6.7 million, an increase of approximately $400,000 or 7% over the fourth quarter of 2009. Versus the prior year's first quarter revenues were down about $2 million or 23%. ***The decrease from the prior year's Q1 was due to the impacts of the reimbursement environment, which began to cause a headwind in the second quarter of 2009.***
> Defendant Reali: I can comment on what our strategy is. I think it is too early to comment on the success or not of that strategy, but I would think about our strategy in three pathways that we are pursuing, which were highlighted on the call today. First off, it is working with the payers to remove our experimental designation over time. And this has to be done on a payer by payer basis.
>
> Secondly, it is working with the spine societies to gain endorsement and acceptance of our procedure in a broad manner. And thirdly, it is working with our physician customers getting further clinical data published and presented at key meetings such as the SAS meeting that was discussed last week.

> First of all, it is still too early to project the success of our current strategy, as I mentioned. I think what we mean is by stabilization is just in our results itself. We are not seeing a decline quarter-over-quarter like we saw in the second half of 2009. What contributes to that? Certainly, we feel some of that is related to our three pronged approach on a reimbursement strategy, which is the current strategy that we are going forward with. And to your point, the endgame is a category one code.
>
> ***Now it is important to remember that the current code we have, which is a T code is not an experimental code. It is a tracking code. What we hope to do in the near term is work with payers to get that tracking code covered.*** Over time, as we evolve on this strategy and we penetrate the market, a decision will be made when we would apply for a category one code. But until we are successful in all parts of our strategy relative to payer acceptance and spine society endorsements and continued publications, we will not submit for a category one code.

89. On May 10, 2010, the Company filed a quarterly report for the period ended March 31, 2010 on Form 10-Q with the SEC, which was signed by Defendants Randall and Slattery and reiterated the Company's previously announced quarterly financial results and financial position. In addition, the Form 10-Q contained signed certifications by Defendants Randall and Slattery, stating that the financial information contained in the Form 10-Q was accurate and that they disclosed any material changes to the Company's internal control over financial reporting. The 10-Q stated in relevant part:

> Revenue. Revenue decreased from $8.7 million in the three months ended March 31, 2009 to $6.7 million in the three months ended March 31, 2010. The $2.0 million decrease in revenue from 2009 to 2010 was related to lower than expected case volume as a result of concerns and uncertainty in the marketplace surrounding physician reimbursement for our AxiaLIF procedure. We are addressing these issues with increased education and support resources for our current and prospective surgeon users. Domestically, sales of our AxiaLIF 2L product decreased from $2.3 million in the three months ended March 31, 2009 to $1.9 million in the three months ended March 31, 2010 and sales of our AxiaLIF 360° product decreased from $2.6 million in the three months ended March 31, 2009 to $1.4 million in the three months ended March 31, 2010. New products accounted for revenue of $132,000 in the first quarter of 2010. Average selling prices in the United States increased from approximately $10,600 in the three months ended March 31, 2009 to approximately $10,700 in the three months ended March 31, 2010. In the three months ended March 31, 2009 and 2010, we recorded 751 and 537 domestic AxiaLIF cases, respectively, including 261 AxiaLIF 360°

cases and 168 AxiaLIF 2L cases in the first quarter of 2009, and 134 AxiaLIF 360° cases and 141 AxiaLIF 2L cases in the first quarter of 2010.

90. The foregoing statements were materially false and misleading for the reasons set forth in ¶ 71.

91. On August 5, 2010, the Company issued a press release announcing its financial results for the second quarter ended June 30, 2010. For the quarter, the Company reported a net loss of $4 million, $0.18 diluted LPS and revenue of $7 million, as compared to a net loss of $7 million, or $0.33 diluted LPS and revenue of $8 million for the same period a year ago.

92. On August 6, 2010, the Company filed a quarterly report for the period ended June 30, 2010 on Form 10-Q with the SEC, which was signed by Defendants Randall and Slattery, and reiterated the Company's previously announced quarterly financial results and financial position. In addition, the Form 10-Q contained signed certifications by Defendants Randall and Slattery, stating that the financial information contained in the Form 10-Q was accurate and that they disclosed any material changes to the Company's internal control over financial reporting. The 10-Q stated in relevant part:

> *Revenue* Revenue decreased from $7.9 million in the three months ended June 30, 2009 to $7.2 million in the three months ended June 30, 2010. The $0.7 million decrease in revenue from 2009 to 2010 was related to lower than expected case volume as a result of concerns and uncertainty in the marketplace surrounding physician reimbursement for our AxiaLIF procedure. Domestically, sales of our AxiaLIF 2L products decreased from $2.3 million in the three months ended June 30, 2009 to $2.2 million in the three months ended June 30, 2010 and sales of our AxiaLIF single level products decreased from $4.4 million in the three months ended June 30, 2009 to $3.6 million in the three months ended June 30, 2010. New products accounted for revenue of $0.4 million in the three months ended June 30, 2010. In the three months ended June 30, 2010, average revenue per AxiaLIF case continued to climb, helped by a price increase effective April 1, 2010, the limited market release of our AxiaLIF 2L+ product, and penetration into existing cases by our new products. In the three months ended June 30, 2009 and 2010, we recorded 671 and 541 domestic AxiaLIF cases, respectively, including 175 AxiaLIF 2L cases in the three months ended June 30, 2009, and 148 AxiaLIF 2L cases in the three months ended June 30, 2010.
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> *Revenue* Revenue decreased from $16.6 million in the six months ended June 30, 2009 to $14.0 million in the six months ended June 30, 2010. The $2.6 million decrease in revenue from 2009 to 2010 was related to lower than expected case volume as a result of concerns and uncertainty in the marketplace surrounding physician reimbursement for our AxiaLIF procedure. Domestically, sales of our AxiaLIF 2L products decreased from $4.6 million in the six months ended June 30, 2009 to $4.1 million in the six months ended June 30, 2010 and sales of our AxiaLIF single level products decreased from $9.5 million in the six months ended June 30, 2009 to $7.0 million in the six months ended June 30, 2010. New products accounted for revenue of $0.5 million in 2010. In the six months ended June 30, 2010, average revenue per AxiaLIF case continued to climb, helped by a price increase effective April 1, 2010, the limited market release of our AxiaLIF 2L+ product in January 2010, and penetration into existing cases by our new products. In the six months ended June 30, 2009 and 2010, we recorded 1,422 and 1,078 domestic AxiaLIF cases, respectively, including 343 AxiaLIF 2L cases in 2009 and 289 AxiaLIF 2L cases in 2010.

93. The foregoing statements were materially false and misleading for the reasons set forth in ¶ 71.

94. On November 9, 2010, the Company issued a press release announcing its financial results for the third quarter ended September 30, 2010. For the quarter, the Company reported a net loss of $3.8 million, or ($0.18) diluted LPS and revenue of $6 million, as compared to a net loss of $5.6 million, or ($0.27) diluted LPS and revenue of $7 million for the same period a year ago.

95. On November 10, 2010, the Company filed a quarterly report for the period ended September 30, 2010 on Form 10-Q with the SEC, which was signed by Defendants Randall and Slattery and reiterated the Company's previously announced quarterly financial results and financial position. In addition, the Form 10-Q contained signed certifications by Defendants Randall and Slattery, stating that the financial information contained in the Form 10-Q was accurate and that they disclosed any material changes to the Company's internal control over financial reporting. The 10-Q stated in relevant part:

> *Revenue* Revenue decreased from $6.9 million in the three months ended September 30, 2009 to $6.3 million in the three months ended September 30, 2010.

The $0.6 million decrease in revenue from 2009 to 2010 was related to lower case volume as a result of concerns and uncertainty in the marketplace surrounding physician reimbursement for our AxiaLIF procedure. Domestically, sales of our AxiaLIF single level products decreased from $4.1 million in the three months ended September 30, 2009 to $3.2 million in the three months ended September 30, 2010, and sales of our AxiaLIF 2L products increased from $1.8 million in the three months ended September 30, 2009 to $1.9 million in the three months ended September 30, 2010. New products accounted for revenue of $0.3 million in the three months ended September 30, 2010. In the three months ended September 30, 2010, average revenue per AxiaLIF case continued to increase, helped by a price increase effective April 1, 2010, the release of our AxiaLIF 2L+ product, and penetration into existing cases by our new products. In the three months ended September 30, 2009 and 2010, we recorded 606 and 490 domestic AxiaLIF cases, respectively, including 138 AxiaLIF 2L cases in the three months ended September 30, 2009, and 136 AxiaLIF 2L and 2L+ cases in the three months ended September 30, 2010.

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Revenue Revenue decreased from $23.5 million in the nine months ended September 30, 2009 to $20.3 million in the nine months ended September 30, 2010. The $3.2 million decrease in revenue from 2009 to 2010 was related to lower case volume as a result of concerns and uncertainty in the marketplace surrounding physician reimbursement for our AxiaLIF procedure. Domestically, sales of our AxiaLIF single level products decreased from $13.1 million in the nine months ended September 30, 2009 to $10.2 million in the nine months ended September 30, 2010 and sales of our AxiaLIF 2L products decreased from $6.2 million in the nine months ended September 30, 2009 to $6.0 million in the nine months ended September 30, 2010. New products accounted for revenue of $0.8 million in the nine months ended September 30, 2010. In the nine months ended September 30, 2010, average revenue per AxiaLIF case continued to increase, helped by a price increase effective April 1, 2010, the full market release of our AxiaLIF 2L+ product, and penetration into existing cases by our new products. In the nine months ended September 30, 2009 and 2010, we recorded 2,028 and 1,568 domestic AxiaLIF cases, respectively, including 481 AxiaLIF 2L cases in 2009 and 425 AxiaLIF 2L and 2L+ cases in 2010.

96. The foregoing statements were materially false and misleading for the reasons set forth in ¶ 71.

97. On February 22, 2011, the Company issued a press release announcing its financial results for the fourth quarter and year ended December 31, 2010. For the fourth quarter, the Company reported a net loss of $5.7 million, or $0.27 diluted LPS and revenue of $5.9 million, as compared to a net loss of $5.7 million, or $0.28 diluted LPS and revenue of $6.3 million for the

same period a year ago. For the year, the Company reported a net loss of $19.5 million, or $0.94 diluted LPS and revenue of $26.2 million, as compared to a net loss of $23.2 million, or $1.13 diluted LPS and revenue of $30 million for the same period a year ago.

98. On March 14, 2011, the Company filed an annual report for the period ended December 31, 2010 on Form 10-K with the SEC, which was signed by, among others, Defendants Reali, Slattery and Randall, and reiterated the Company's previously announced annual financial results and financial position. In addition, the Form 10-K contained signed certifications by Defendants Reali and Slattery, stating that the financial information contained in the Form 10-K was accurate and that they disclosed any material changes to the Company's internal control over financial reporting.

99. The 10-K represented the following:

> "Our revenue is primarily derived from sales of our AxiaLIF products and related surgical instruments. We expect that sales of our AxiaLIF products will continue to account for a substantial portion of our revenues for the foreseeable future."
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> *Drive Reimbursement for Our Procedure.* We will continue to work with our surgeon customers to generate published, peer reviewed clinical literature that demonstrates our procedure's clinical efficacy and safety. We will also work to leverage this data along with our AxiaLIF surgeon advocates, with payors to secure positive coverage decisions for the reimbursement of the AxiaLIF procedure.
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> Surgeons use the American Medical Association's Current Procedural Terminology, or CPT, system to bill payors for the AxiaLIF procedures. CPT codes describe the services and procedures provided for patients to third party payors so that physicians may be reimbursed. Effective January 1, 2009, the AMA implemented a Category III code which may describe the work involved in treating some AxiaLIF patients. Unlike Category I CPT codes, Category III codes do not have a set value which physicians use as a benchmark for setting their fee. Additionally, ***some payors view Category III codes as "investigational" or "experimental" and may not reimburse them.*** However, unlike many new or novel procedures, AxiaLIF is an access variation on the current standard of care (interbody spinal fusion) and has been performed in over 10,000 U.S. procedures.

> In December 2010, Humana Inc. made a decision to cover the AxiaLIF procedures and reimburse physicians for use of the Category III Code. The reimbursement rates are consistent with reimbursement levels for performing other interbody fusion procedures. We intend to gain further positive reimbursement coverage decisions with other payors in the coming quarters by utilizing published clinical literature and leveraging the support of physicians that perform our procedures. Discussions are normally held with medical directors representing the payors to inform them that our approach to interbody fusion is not "investigational" or "experimental."
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> ***
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> To access the spine using our pre-sacral approach, the surgeon creates a small incision adjacent to the tailbone while the patient is lying on their stomach.

100. The foregoing statements were materially false and misleading for the reasons set forth in ¶ 71.

101. On May 12, 2011, the Company issued a press release announcing its financial results for the first quarter ended March 31, 2011. For the quarter, the Company reported a net loss of $5.7 million, or $0.27 diluted LPS and revenue of $5.1 million, as compared to a net loss of $6.4 million, or $0.31 diluted LPS and revenue of $6.7 million for the same period a year ago.

102. On May 16, 2011, the Company filed a quarterly report for the period ended March 31, 2011 on Form 10-Q with the SEC, which was signed by Defendants Reali and Slattery and reiterated the Company's previously announced quarterly financial results and financial position. In addition, the Form 10-Q contained signed certifications by Defendants Reali and Slattery, stating that the financial information contained in the Form 10-Q was accurate and that they disclosed any material changes to the Company's internal control over financial reporting. The 10-Q stated in relevant part:

> *Revenue.* Revenue decreased from $6.7 million in the three months ended March 31, 2010 to $5.1 million in the three months ended March 31, 2011. The $1.6 million decrease in revenue from 2010 to 2011 was primarily a result of a lower number of AxiaLIF cases performed in 2011, which was due primarily to physician reimbursement limitations and insurance denials for lumbar fusion surgery due to medical necessity. Domestically, sales of our AxiaLIF 1L products decreased from $3.5 million in the three months ended March 31, 2010 to

> $2.5 million in the three months ended March 31, 2011, and sales of our AxiaLIF 2L products decreased from $1.9 million in the three months ended March 31, 2010 to $1.5 million in the three months ended March 31, 2011. Sales of our pedicle screw system, which was introduced in January 2010, were $0.1 million for the three months ended March 31, 2010 and 2011 and sales of our Bi-Ostetic bone void filler, which we introduced in February 2010, increased from $17,000 in the three months ended March 31, 2010 to $0.2 million in the three months ended March 31, 2011. In the three months ended March 31, 2011, average revenue per AxiaLIF case continued to increase, helped by a price increase effective April 1, 2010, the release of our AxiaLIF 2L+ product in July 2010, and penetration into existing cases by our new products. In the three months ended March 31, 2010 and 2011, we recorded 537 and 369 domestic AxiaLIF cases, respectively, including 141 AxiaLIF 2L cases in the three months ended March 31, 2010, and 102 AxiaLIF 2L and 2L+ cases in the three months ended March 31, 2011.

103. The foregoing statements were materially false and misleading for the reasons set forth in ¶ 71.

104. On August 9, 2011, the Company issued a press release announcing its financial results for the second quarter ended June 30, 2011. For the quarter, the Company reported a net loss of $4.3 million, or $0.21 diluted LPS and revenue of $5.3 million, as compared to a net loss of $3.6 million, or $0.18 diluted LPS and revenue of $7.2 million for the same period a year ago.

105. On August 11, 2011, the Company filed a quarterly report for the period ended June 30, 2011 on Form 10-Q with the SEC, which was signed by Defendants Reali and Slattery, and reiterated the Company's previously announced quarterly financial results and financial position. In addition, the Form 10-Q contained signed certifications by Defendants Reali and Slattery, stating that the financial information contained in the Form 10-Q was accurate and that they disclosed any material changes to the Company's internal control over financial reporting.

106. The foregoing statements were materially false and misleading for the reasons set forth in ¶ 71.

107. On September 21, 2011, the Company announced that it had priced a public offering of 6.2 million shares of its common stock at a price of $3.25 per share. The gross proceeds

to Trans1 from the sale of shares, before expenses and any over-allotment exercise were expected to be $20,150,000.

THE TRUTH BEGINS TO EMERGE

108. The Company's rampant reimbursement scheme inevitably drew regulatory scrutiny, especially in light of the qui tam Complaint filed in April, 2011. . Six months later, on October 17, 2011, after the market closed, the Company filed a Form 8-K with the SEC, where it disclosed the following:

> On or about October 6, 2011, TranS1 Inc. (the "Company") received a subpoena issued by the Department of Health and Human Services, Office of Inspector General, under the authority of the federal healthcare fraud and false claims statutes. The subpoena seeks documents for the period January 1, 2008 through October 6, 2011. The Company is cooperating with the government's request and is in the process of responding to the subpoena. The Company is unable to predict what action, if any, might be taken in the future by the Department of Health and Human Services, Office of Inspector General or other governmental authorities as a result of the matters related to this subpoena or what impact, if any, the outcome of these matters might have on its consolidated financial position, results of operations, or cash flows. No claims have been made against the Company at this time.

109. The market quickly realized that insurance company reimbursement for the AxiaLIF procedure was the focus of the subpoena, given that AxiaLIF is Trans1's flagship product and accounts for a majority of its revenue. The market's realization is evidenced by a McNicoll Lewis Vlak ("MLV") analyst report published on October 18, 2011, which stated that the subpoena "included 19 items ranging from patient names to serial lot traceability to reimbursement communications with physicians." Further, the report noted the following:

> Management mentioned in our conversation that they have 'let so many reps go in the last year and a half' (due to downsizing), which makes us think the subpoena could perhaps stem from allegations by a disgruntled former employee. Another speculation would be since about half of TranS1's revenues come from physicians still using the ALIF code (which provides reimbursement), rather than the designated T-code (which does not provide reimbursement), the issue could be due to reimbursement communications, although we think that the Company has been

> making strong efforts to educate physicians about correct coding. Note that ultimately the decision regarding which code to use lies in the hands of the physician.

110. Thus, the market fully apprehended the following facts from the Company's disclosure: 1) the investigation related to the Company's reimbursement practices for AxiaLIF; and 2) the investigation was triggered by a whistleblower former employee. The market's interpretation of the October 17 disclosure was fully validated by the allegations of the government as set forth in the June 28, 2013 settlement agreement, as well as the concurrent unsealing of the qui tam Complaint.

111. On this news, Trans1's securities plummeted $1.27 or 40.7%, to close at $1.85 on October 18, 2011.

Additional Scienter Allegations

112. The Individual Defendants, as directors and/or officers of Trans1 during the Class Period, are liable as direct participants in all of the wrongs complained of herein. Through their positions of control and authority, these Defendants were in a position to, and did, control all of the Company's false and misleading statements and omissions, including the contents of SEC filings and press releases, as set forth herein.

113. The Individual Defendants cannot credibly claim that they were unaware of the improper reimbursement scheme. As explained *infra*, AxiaLIF, the Company's key product, represented its primary source of revenue. Moreover, throughout the Class Period, Individual Defendants made numerous statements regarding the challenges incurred because of the Category III designation for AxiaLIF. Further, Amy Connors, the head of Trans1's reimbursement committee, made a number of presentations to management and the Board of Directors regarding reimbursement issues in light of the AMA's Category III designation. As such, it is inconceivable

that the Company's executives were unaware of Trans1's pervasive scheme to evade AxiaLIF's Category III assignment. To the extent that they were unaware of this scheme, such a blatant disregard for the obvious bespeaks their recklessness.

114. In addition, the Company employed less than 130 individuals rendering it highly unlikely that the Individual Defendants, the Company's key executives and decision makers, were unaware of the major activities transpiring within the Company.

115. Additionally, Defendant Randall attended the Company's National Meeting in January 2009 held in Nevada, where Defendants publicly promoted using anterior coding for the AxiaLIF procedure, despite the implementation of the Category III code for AxiaLIF that same month.

116. Further, during the Class Period, between May 26, 2010 and May 27, 2010, Defendant Randall disposed of a massive 100,000 shares of Company stock at inflated prices. He sold an additional 20,000 shares of stock at inflated prices on August 17, 2011. Notably, Randall did not sell any shares of Company stock either before or after the Class Period. At the time of these sales, Randall was well aware of the Company's rampant reimbursement scheme.

117. These allegations are not only corroborated by the recently unsealed qui Tam Complaint filed by plaintiff and Relator Kevin Ryan on April 21, 2011 in the District of Maryland, as set forth above, but also by the Settlement Agreement, attached hereto and effective June 28, 2013, between Trans1 and the United States Department of Justice on behalf of the Office of Inspector General of the Department of Health and Human Services ("OIG-HHS"), the TRICARE Management Activity ("TMA"), the United States Office of Personnel Management ("OPM"), the United States Department of Veterans Affairs ("VA"), and Office of Workers' Compensation Programs of the United States Department of Labor ("DOL-OWCP") (collectively the United

States"); Kevin J. Ryan ("Relator"). The Settlement Agreement resolves claims, confirming those in the instant Complaint, that:

> (1) TranS 1 knowingly caused providers to submit claims for minimally invasive AxiaLIF procedures using incorrect diagnosis or procedure codes, including codes intended for invasive ALIF procedures, such as 22558, or for unlisted spine procedures, 22899, which In some cases resulted in providers receiving greater reimbursement than that to which they were entitled; (2) TranS 1 knowingly offered and paid illegal remuneration to certain physician providers for participating in speaker programs and consultant meetings in a manner intended to induce them to use TranS 1 products in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b); and (3) TranS1 knowingly promoted the sale and use of axial lumbar interbody fusion devices for uses that were not approved or cleared by FDA including in certain spine procedures involving complex deformity affecting vertebral levels other than the levels for which AxiaLIF is FDA-cleared. Some of these uses were not reasonable and necessary for the diagnosis or treatment of an illness 01' injury, contrary to 42 U.S.C. § 1395y(a)(I)(A), and thus were not covered by Medicare, Medicaid, or the Other Federal Health Care Programs.

118. Pursuant to the Settlement Agreement, Trans1 is required to pay $6 million, which represents 28% of its reported cash and short term investments. Such a large percentage contributes to the compelling inference of Defendants' scienter.

119. The Settlement Agreement further requires that Trans1 maintain its current compliance program and undertake a series of compliance related obligations, including training and monitoring procedures and maintaining a disciplinary process for compliance obligations for five years.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

120. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Trans1 securities during the Class Period (the "Class"); and were damaged thereby. Excluded from the Class are defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

121. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Trans1 securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Trans1 or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

122. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by defendants' wrongful conduct in violation of federal law that is complained of herein.

123. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

124. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by defendants' acts as alleged herein;
- whether statements made by defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Trans1;
- whether the Individual Defendants caused Trans1 to issue false and misleading financial statements during the Class Period;
- whether defendants acted knowingly or recklessly in issuing false and misleading financial statements;

- whether the prices of Trans1 securities during the Class Period were artificially inflated because of the defendants' conduct complained of herein; and

- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

125. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

126. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- defendants made public misrepresentations or failed to disclose material facts during the Class Period;

- the omissions and misrepresentations were material;

- Trans1 securities are traded in an efficient market;

- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;

- the Company traded on the NASDAQ and was covered by multiple analysts;

- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

- Plaintiff and members of the Class purchased and/or sold Trans1 securities between the time the defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

127. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

COUNT I

(Against All Defendants For Violations of Section 10(b) And Rule 10b-5 Promulgated Thereunder)

128. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

129. This Count is asserted against defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

130. During the Class Period, defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Trans1 securities; and (iii) cause Plaintiff and other members of the Class to purchase Trans1 securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, defendants, and each of them, took the actions set forth herein.

131. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Trans1 securities. Such reports, filings, releases and statements were

materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Trans1's finances and business prospects.

132. By virtue of their positions at Trans1, defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to defendants. Said acts and omissions of defendants were committed willfully or with reckless disregard for the truth. In addition, each defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

133. Defendants were personally motivated to make false statements and omit material information necessary to make the statements not misleading in order to personally benefit from the sale of Trans1 securities from their personal portfolios.

134. Information showing that defendants acted knowingly or with reckless disregard for the truth is peculiarly within defendants' knowledge and control. As the senior managers and/or directors of Trans1, the Individual Defendants had knowledge of the details of Trans1 internal affairs.

135. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Trans1. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Trans1's businesses,

operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Trans1 securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Trans1's business and financial condition which were concealed by defendants, Plaintiff and the other members of the Class purchased Trans1 securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by defendants, and were damaged thereby.

136. During the Class Period, Trans1 securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased shares of Trans1 securities at prices artificially inflated by defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased said securities, or would not have purchased them at the inflated prices that were paid. At the time of the purchases by Plaintiff and the Class, the true value of Trans1 securities were substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Trans1 securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

137. By reason of the conduct alleged herein, defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

138. As a direct and proximate result of defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and

sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against The Individual Defendants)

139. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

140. During the Class Period, the Individual Defendants participated in the operation and management of Trans1, and conducted and participated, directly and indirectly, in the conduct of Trans1's business affairs. Because of their senior positions, they knew the adverse non-public information about Trans1's misstatement of income and expenses and false financial statements.

141. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Trans1's financial condition and results of operations, and to correct promptly any public statements issued by Trans1 which had become materially false or misleading.

142. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Trans1 disseminated in the marketplace during the Class Period concerning Trans1's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Trans1 to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of Trans1 within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Trans1 securities.

143. Each of the Individual Defendants, therefore, acted as a controlling person of Trans1. By reason of their senior management positions and/or being directors of Trans1, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Trans1 to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Trans1 and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

144. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Trans1.

PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiff demands judgment against defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Lead Plaintiff as the Class representative;

B. Requiring defendants to pay damages sustained by Lead Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Lead Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Lead Plaintiff hereby demands a trial by jury.

Dated: August 9, 2013

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